DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

RADIOMETER MEDICAL APS
SOEREN BØEGESTRAND
SENIOR REGULATORY AFFAIRS SPECIALIST
AAKANDEVEJ 21
BROENSHOEJ DK-2700, DENMARK

November 4, 2016

Re: K160153
Trade/Device Name: ABL 90 FLEX PLUS
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL, CEM, JGS, CGZ, CGA, KHP, GHS, GKR, KQI, JIX, JJY, MQM, JFP
Dated: October 05, 2016
Received: October 07, 2016

Dear Soeren Boegestrand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160153

Device Name
ABL90 FLEX PLUS

Indications for Use *(Describe)*
The ABL90 FLEX PLUS analyzer is an in vitro diagnostic, portable, automated analyser that quantitatively measures, pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinized whole blood, and neonatal bilirubin in heparinized capillary whole blood.

The ABL90 FLEX PLUS analyzer is intended for use by trained technologists, nurses, physicians and therapists.

It is intended for use in a laboratory environment, near patient or point-of-care setting.

These tests are only performed under a physician's order.

Bilirubin measurements on the ABL90 FLEX PLUS analyzer are intended to aid in assessing the risk of kernicterus in neonates.

pH, pO2 and pCO2: pH, pCO2 and pO2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium (cK+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration,inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Calcium (cCa2+): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride (cCl–): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

Glucose (cGlu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (cLac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)

Total Hemoglobin (ctHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

FO2Hb: oxyhemoglobin as a fraction of total hemoglobin.

FCOHb: carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

FMetHb: methemoglobin as a fraction of total hemoglobin.

FHHb: reduced hemoglobin as a fraction of total hemoglobin.

Fraction of Fetal Hemoglobin (FHbF): FHbF indicates the amount of fetal hemoglobin. FHbF is seldom used clinically.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

1. Submitter and contact information

Submitter
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Date prepared
Date: November 4, 2016

2. a. Device Information

Device Name: ABL90 FLEX PLUS
Common Name: Blood gases (pCO_2, pO_2) and blood pH test system.

Classification:

Classification name	CFR Section	Device Class	Product Code
Electrode measurement, blood-gases (pCO_2, pO_2) and blood pH	862.1120	II	CHL
Potassium test system	862.1600	II	CEM
Sodium test system	862.1665	II	JGS
Chloride test system	862.1170	II	CGZ
Glucose test system	862.1345	II	CGA
Carboxyhemoglobin assay	864.7425	II	GHS
Automated hemoglobin system	864.5620	II	GKR
Fetal hemoglobin assay	864.7455	II	KQI
Calibrator	862.1150	II	JIX
Calcium test system	862.1145	II	JFP

Quality control material (assayed and unassayed)	862.1660	I	JJY
Bilirubin (total and unbound) in the neonate test system	862.1113	I	MQM
Lactic acid test system	862.1450	I	KHP

2. b. Device Description

Instrument name, manufacturer, models and accessories

The ABL90 FLEX PLUS is a portable, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, neonatal bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, *F*COHb, *F*MetHb, *F*HHb and *F*HbF).

The manufacturer of the ABL90 FLEX PLUS is Radiometer Medical ApS.

The ABL90 FLEX PLUS consists of an instrument with a sensor cassette and a solution pack as the main accessories. Multiple models of sensor cassettes are available.

The various sensor cassette models include models for different parameter combinations. For each parameter combination, models allowing for different test load are available. The solution pack is available in two models differing in the number of tests available.

2. c. Purpose of submission

The purpose of this submission is to seek clearance for a design change to the existing ABL90 FLEX analyzer. The design change will result in the introduction of an additional variant of the ABL90 FLEX analyzer called ABL90 FLEX PLUS. To accommodate this, the ABL90 FLEX analyzer has been changed as outlined below:

- The inlet module on the ABL90 FLEX PLUS analyzer has been mechanized, the mechanized inlet module is in multiple places in this 510(k) referred to as the AutoInlet. The opening and closing of the inlet is either button activated using the touch screen or in certain cases automatic when appropriate. The mechanized inlet module subsequently calls for the following derived changes listed below.
- Addition of the Short Probe Mode measuring mode on the ABL90 FLEX PLUS. In ABL90 FLEX, a little plastic clip (ABL90 FLEX Inlet Clip) component to be placed on the ABL90 FLEX inlet when using non-Radiometer samplers is incorporated. The purpose of the inlet clip is to shorten the maximum travel of the inlet into the sampler and thereby reduce the sample volume required. The use of an inlet clip for blood measurements is no longer relevant with the introduction of the Short Probe Mode. On the ABL90 FLEX PLUS, the short probe position has been built directly into the analyzer to replace the use of the inlet clip allowing the user the option of the standard syringe mode or the Short Probe Mode.
- Modifications to software to support both ABL90 FLEX and ABL90 FLEX PLUS. The modifications in the software relevant to this application are the support of the mechanized inlet module in ABL90 FLEX PLUS (including the Short Probe Mode), as well as the ability to distinguish and detect the type of inlet (manual or mechanized) an analyzer is fitted with.
- Instructions for Use for ABL90 FLEX PLUS have been established.

Except for the above identified modifications and minor differences in visual appearance the ABL90 FLEX and ABL90 FLEX PLUS analyzers are identical. Both analyzers use the same software version and have the same accessories.

3. Intended Use/Indications for use

The ABL90 FLEX PLUS analyzer is an in vitro diagnostic, portable, automated analyser that quantitatively measures, pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinized whole blood, and neonatal bilirubin in heparinized capillary whole blood.

The ABL90 FLEX PLUS analyzer is intended for use by trained technologists, nurses, physicians and therapists.

It is intended for use in a laboratory environment, near patient or point-of-care setting.

These tests are only performed under a physician's order.

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Sodium (cNa+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration,inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Calcium (cCa2+): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride (cCl–): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

Glucose (cGlu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (cLac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)

Total Hemoglobin (ctHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

FO2Hb: oxyhemoglobin as a fraction of total hemoglobin.

FCOHb: carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

FMetHb: methemoglobin as a fraction of total hemoglobin.

FHHb: reduced hemoglobin as a fraction of total hemoglobin.

Fraction of Fetal Hemoglobin (FHbF): FHbF indicates the amount of fetal hemoglobin. FHbF is seldom used clinically.

4. Predicate device: ABL90 FLEX (K132691)
Substantial Equivalence
The ABL90 FLEX PLUS analyzer is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate devices:

Predicate Device: 510(k) Number, Name, Device Manufacturer:
K132691, ABL90 FLEX, Radiometer Medical ApS
K131988, ABL90 FLEX, Radiometer Medical ApS

Similarities		
Issue	**SE Device**	**Predicate Devices (K132691, K131988)**
Parameters	Same	pH, pO_2, pCO_2, sodium, potassium, calcium, chloride, glucose, lactate, sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HHB, *F*HbF, neonatal bilirubin.
Measuring method	Same	Potentiometry, Amperometry, Optical pO_2 ,Spectrophotometry
Calibration Method	Same	Two-point liquid calibration
Intended Use	Same	The ABL90 FLEX analyzer is an in vitro diagnostic, portable, automated analyser that quantitatively measures, pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinized whole blood, and neonatal bilirubin in heparinized capillary whole blood. The ABL90 FLEX analyzer is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order. Bilirubin measurements on the ABL90 FLEX analyzer are intended to aid in assessing the risk of kernicterus in neonates.
Intended use site	Same	Laboratory and point-of-care.

Differences		
Issue	**SE Device**	**Predicate Devices (K132691, K131988)**
Inlet	Mechanized inlet	Manual inlet
Short probe mode	Yes	No

5. Performance Characteristics

No performance data are affected by the change. The existing performance data still apply.

Verification of the ABL90 FLEX PLUS showed that the precision performance of all three modes of the ABL90 FLEX PLUS is equivalent to the precision performance of ABL90 FLEX for the 17 parameters available on the analyzers: pH, $p\mathrm{CO_2}$, $p\mathrm{O_2}$, $c\mathrm{Ca^{2+}}$, $c\mathrm{Cl^-}$, $c\mathrm{K^+}$, $c\mathrm{Na^+}$, *c*Glu, *c*Lac, *c*tHb, $s\mathrm{O_2}$, $F\mathrm{O_2Hb}$, *F*HHb, *F*MetHb, *F*COHb, *F*HbF, and neonatal bilirubin.

The existing clinical precision performance claims in the manual for ABL90 FLEX are also applicable to ABL90 FLEX PLUS.

Verification of the ABL90 FLEX PLUS Short Probe mode showed that measurements performed with ABL90 FLEX PLUS in Short Probe mode are equivalent to measurements performed with ABL90 FLEX in syringe mode with inlet clip for the 17 parameters available on the analyzers: pH, $p\mathrm{CO_2}$, $p\mathrm{O_2}$, $c\mathrm{Ca^{2+}}$, $c\mathrm{Cl^-}$, $c\mathrm{K^+}$, $c\mathrm{Na^+}$, *c*Glu, *c*Lac, *c*tHb, $s\mathrm{O_2}$, $F\mathrm{O_2Hb}$, *F*HHb, *F*MetHb, *F*COHb, *F*HbF, and neonatal bilirubin.

The existing clinical method comparison claims in the manual for ABL90 FLEX syringe mode are applicable to ABL90 FLEX PLUS Short Probe mode.

6. Summary of Design Control activities

Risk Assessment:

We conducted an FMEA risk analysis and mitigated all identified hazards to As Low As Reasonably Practicable (ALARP) per ISO 14971, and verified mitigations by using test protocols. Results met predefined acceptance criteria

Performance testing:

Issue	Acceptance criteria	Verification method	Result and Pass/Fail	Comments
Method comparison of ABL90 FLEX PLUS Short Probe mode versus ABL90 FLEX syringe mode with inlet clip	Data analysis by linear regression must result in: • Slope between 0.95 and 1.05 • Coefficient of determination R^2>0.97 • Intercepts: pH: ±0.75 pO_2: ±11 mmHg pCO_2: ±4.5 mmHg Cl^-: ±11 mM Na^+: ±15 mM K^+: ±0.5 mM Ca^{2+}: ±0.5 mM Glucose: ±0.6 mmol/L Lactate: ±0.4 mmol/L tHb: ±1.5 g/dL sO_2: ±10% FO_2Hb: ±10% FCOHb: ±1% FMetHb: ±1% FHHb: ±2.4% FHbF: ±21% Neonatal bilirubin: ±28 µmol/L	In-house method comparison study of ABL90 FLEX PLUS Short Probe mode versus ABL90 FLEX syringe mode with inlet clip with more than 40 samples (N) per parameter spanning the measuring range. Each sample was analyzed in singlicate. For each parameter, less than 20% of the samples were spiked. Samples were heparinized, leftover whole blood samples (analyzed 2-3 hours post draw).	Data analysis by linear regression showed: • Slopes were between 0.95 and 1.05. • Coefficients of determination R^2 were >0.97. • Intercepts were within acceptance criteria. Pass.	Existing method comparison claims for ABL90 FLEX syringe mode apply to ABL90 FLEX PLUS Short Probe mode.

Issue	Acceptance criteria	Verification method	Result and Pass/Fail	Comments
Imprecision	The same or better clinical precision than originally determined for ABL90 FLEX (K092686 and K132691). The within-run (S_r) and total imprecision (S_T) pooled across sites must be the same or better than originally determined for ABL90 FLEX (K092686 and K132691) at a 95% confidence level using a Chi-square test. The acceptance criteria have been itemized in the below table.	Point-of-care precision studies on ABL90 FLEX PLUS syringe, short probe, and capillary mode were performed at 3 point-of care sites over at least 20 days, with 2 runs per day and 2 replicates per run. Samples were spiked whole blood except for neonatal bilirubin for which samples were aqueous solutions. For FHbF, the sample material was cord blood. Fresh whole blood samples were prepared each test day. To eliminate the sample-to-sample imprecision contribution, the total imprecision for all parameters except neonatal bilirubin was calculated as the imprecision of the bias towards a reference value determined for each sample on an ABL90 FLEX reference instrument.	All within-run and total imprecisions were within the acceptance criteria. Pass	Existing clinical precision claims for ABL90 FLEX apply to ABL90 FLEX PLUS.

Imprecision acceptance criteria

Analyte	Level	S_r (within-run)	%CV (within-run)	S_T (total)	%CV (total)
Capillary mode					
pH	7.27	0.0030	0.04	0.0056	0.08
	7.38	0.0028	0.04	0.0065	0.09
	7.47	0.0032	0.04	0.0067	0.09
pCO_2 (mmHg)	28	0.71	2.54	0.86	3.07
	42	0.76	1.81	1.13	2.69
	61	1.04	1.70	1.51	2.48
pO_2 (mmHg)	45	0.56	1.24	1.21	2.69
	77	0.94	1.22	1.86	2.42
	205	2.45	1.20	4.82	2.35
cCa^{2+} (mmol/L)	0.58	0.021	3.62	0.032	5.52
	1.21	0.009	0.74	0.029	2.40
	1.89	0.036	1.90	0.070	3.70
cCl^- (mmol/L)	94	0.38	0.40	1.41	1.50
	108	0.43	0.40	1.83	1.69
	122	0.37	0.30	1.69	1.39
cK^+ (mmol/L)	4.8	0.05	1.04	0.12	2.50
	6.6	0.04	0.61	0.09	1.36
cNa^+ (mmol/L)	120	0.36	0.30	0.90	0.75
	141	0.48	0.34	1.15	0.82
	151	0.48	0.32	1.15	0.76
*c*Glu (mmol/L)	0.78	0.04	5.13	0.11	14.10
	5.5	0.09	1.64	0.23	4.18
	15.1	0.23	1.52	0.77	5.10
*c*Lac (mmol/L)	2.1	0.09	4.29	0.17	8.10
	16.1	0.44	2.73	1.56	9.69
*c*tHb (g/dL)	3.7	0.07	1.89	0.09	2.43
	15	0.15	1.00	0.33	2.20
	21.6	0.20	0.93	0.28	1.30
sO_2 (%)	76	0.30	0.39	0.61	0.80
	93	0.20	0.22	0.45	0.48
	100	0.11	0.11	0.20	0.20
*F*COHb (%)	3.2	0.04	1.25	0.29	9.06
	37.3	0.04	0.11	0.32	0.86
*F*MetHb (%)	3.4	0.11	3.24	0.33	9.71
	10.0	0.13	1.30	0.29	2.90
*F*HHb (%)	6.6	0.26	3.94	0.50	7.58
	23.8	0.26	1.09	0.60	2.52
FO_2Hb (%)	74	0.30	0.41	0.67	0.91
	89	0.28	0.31	0.44	0.49
	97	0.20	0.21	0.29	0.30
*F*HbF (%)	42	2.86	6.81	7.07	16.83
	64	2.89	4.52	7.08	11.06
Neonatal bilirubin (µmol /L)	36	0.92	2.56	1.77	4.92
	127	1.85	1.46	2.55	2.01
	523	7.07	1.35	9.41	1.80

Analyte	Level	Sr (within-run)	%CV (within-run)	ST (total)	%CV (total)
Syringe mode					
pH	7.27	0.0023	0.03	0.0047	0.06
	7.37	0.0015	0.02	0.0045	0.06
	7.47	0.0013	0.02	0.0060	0.08
pCO_2 (mmHg)	28	0.66	2.36	0.86	3.07
	42	0.77	1.83	1.10	2.62
	60	1.15	1.92	1.83	3.05
pO_2 (mmHg)	45	0.27	0.60	0.90	2.00
	76	0.84	1.11	1.43	1.88
	204	1.82	0.89	3.54	1.74
cCa^{2+} (mmol/L)	0.58	0.003	0.52	0.022	3.79
	1.21	0.009	0.74	0.026	2.15
	1.89	0.009	0.48	0.042	2.22
cCl^- (mmol/L)	94	0.25	0.27	1.38	1.47
	108	0.42	0.39	1.82	1.69
	122	0.24	0.20	1.32	1.08
cK^+ (mmol/L)	4.8	0.04	0.83	0.08	1.67
	6.6	0.03	0.45	0.08	1.21
cNa^+ (mmol/L)	119	0.36	0.30	0.77	0.65
	141	0.48	0.34	0.90	0.64
	151	0.36	0.24	0.90	0.60
*c*Glu (mmol/L)	0.73	0.04	5.48	0.09	12.33
	5.5	0.05	0.91	0.23	4.18
	14.7	0.18	1.22	0.64	4.35
*c*Lac (mmol/L)	2.2	0.07	3.18	0.18	8.18
	16.2	0.51	3.15	1.94	11.98
*c*tHb (g/dL)	3.8	0.07	1.84	0.12	3.16
	15	0.11	0.73	0.17	1.13
	21.7	0.14	0.65	0.20	0.92
sO_2 (%)	75	0.29	0.39	0.49	0.65
	93	0.17	0.18	0.44	0.47
	100	0.11	0.11	0.22	0.22
*F*COHb (%)	3.2	0.06	1.88	0.28	8.75
	38.0	0.08	0.21	0.32	0.84
*F*MetHb (%)	3.4	0.09	2.65	0.23	6.76
	10.1	0.08	0.79	0.30	2.97
*F*HHb (%)	6.7	0.17	2.54	0.40	5.97
	24.3	0.25	1.03	0.41	1.69
FO_2Hb (%)	72	0.28	0.39	0.59	0.82
	91	0.32	0.35	0.45	0.49
	97	0.18	0.19	0.26	0.27
*F*HbF (%)	41	2.32	5.66	6.37	15.54
	64	4.56	7.13	8.76	13.69
Neonatal bilirubin (µmol/L)	36	1.19	3.31	2.12	5.89
	127	1.35	1.06	2.48	1.95
	525	4.46	0.85	9.15	1.74

Analyte	Level	Sr (within-run)	%CV (within-run)	ST (total)	%CV (total)
Short probe mode					
pH	7.27	0.002	0.03	0.005	0.06
	7.37	0.002	0.02	0.005	0.06
	7.47	0.001	0.02	0.006	0.08
pCO_2 (mmHg)	28	0.66	2.36	0.86	3.07
	42	0.77	1.83	1.10	2.62
	60	1.15	1.92	1.83	3.05
pO_2 (mmHg)	45	0.27	0.60	0.90	2.00
	76	0.84	1.11	1.43	1.88
	204	1.82	0.89	3.53	1.73
cCa^{2+} (mmol/L)	0.58	0.003	0.52	0.02	3.79
	1.21	0.009	0.74	0.03	2.15
	1.89	0.009	0.48	0.04	2.22
cCl^- (mmol/L)	94	0.25	0.27	1.38	1.47
	108	0.42	0.39	1.82	1.69
	122	0.24	0.20	1.32	1.08
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cNa^+ (mmol/L)	119	0.36	0.30	0.77	0.65
	141	0.48	0.34	0.90	0.64
	151	0.36	0.24	0.90	0.60
*c*Glu (mmol/L)	0.73	0.04	5.48	0.09	12.33
	5.5	0.05	0.91	0.23	4.18
	14.7	0.18	1.22	0.65	4.42
*c*Lac (mmol/L)	2.2	0.07	3.18	0.18	8.18
	16.2	0.51	3.15	1.94	11.98
*c*tHb (g/dL)	3.8	0.07	1.84	0.12	3.16
	15	0.11	0.73	0.17	1.13
	21.7	0.14	0.65	0.20	0.92
sO_2 (%)	75	0.29	0.39	0.49	0.65
	93	0.17	0.18	0.44	0.47
	100	0.11	0.11	0.22	0.22
*F*COHb (%)	3.2	0.06	1.88	0.28	8.75
	38.0	0.08	0.21	0.32	0.84
*F*MetHb (%)	3.4	0.09	2.65	0.22	6.47
	10.1	0.08	0.79	0.30	2.97
*F*HHb (%)	6.7	0.17	2.54	0.40	5.97
	24.3	0.25	1.03	0.41	1.69
FO_2Hb (%)	72	0.28	0.39	0.59	0.82
	91	0.32	0.35	0.45	0.49
	97	0.18	0.19	0.26	0.27
*F*HbF (%)	41	2.32	5.66	6.37	15.54
	64	4.56	7.13	8.76	13.69
Neonatal bilirubin (µmol/L)	36	1.19	3.31	2.12	5.89
	127	1.35	1.06	2.48	1.95
	525	4.46	0.85	9.14	1.74

7. Conclusion

Based on the substantial equivalence comparison and the results of the conducted performance evaluations it has been concluded that the ABL90 FLEX PLUS is as safe and effective as the predicate device.